

*Field of the Invention* NEEDLE ARRANGEMENT  
*Background*

1 The invention relates to a needle arrangement for an injection device.

2 A needle arrangement of this kind is known from EP 0 749 758 A1.

3 In it, a hollow needle that is mounted on a hollow needle holder is used.

4 The latter is screwed onto an external thread at the proximal end of the injection  
5 device. A special apparatus which makes the hollow needle invisible to the user,  
6 so as to eliminate his or her anxiety regarding injections, is then slid over this  
7 hollow needle.

*Summary of the Invention*

8 It is the object of the invention to make available a new needle arrangement  
9 for an injection device.

10 According to the invention, this object is achieved by

*Ins 1* ~~the subject matter of Claim 1.~~

12 A needle arrangement of this kind is very easy to utilize, since in practice it  
13 uses nothing more than a replaceable hollow needle. Easy adjustment of the  
14 penetration depth is also achieved, since the necessary penetration depth may be  
15 different depending on the patient's constitution. In this instance, it can be  
16 adjusted easily and obviously.

17 Another manner of achieving the stated object is

*Ins 2* ~~evident from the subject matter of Claim 10.~~

19 An arrangement of this kind has only a few parts and thus can be produced very  
20 economically. It can be used by the patient in a simple, easily understandable  
21 fashion.

22 A further manner of achieving the stated object is

*Ins 3* ~~evident from the subject matter of Claim 30.~~

24 A needle arrangement of this kind can very easily be kept sterile until used. The  
25 covering cap is usable as an assembly aid, additionally facilitating use by the  
26 patient.

27 Each time the patient thrusts the hollow needle in prior to an

NEEDLE ARRANGEMENT

1 The invention relates to a needle arrangement for an injection device.

2 A needle arrangement of this kind is known from EP 0 749 758 A1 or from  
3 DE-U1-8 909 799.8. In it, a hollow needle that is mounted on a hollow needle  
4 holder is used. The latter is screwed onto an external thread at the proximal  
5 end of the injection device. A special apparatus which makes the hollow needle  
6 invisible to the user, so as to eliminate his or her anxiety regarding  
7 injections, is then slid over this hollow needle.

8 It is the object of the invention to make available a new needle  
9 arrangement for an injection device.

10 According to the invention, this object is achieved by  
11 the subject matter of Claim 1.

12 A needle arrangement of this kind is very easy to utilize, since in practice it  
13 uses nothing more than a replaceable hollow needle. Easy adjustment of the  
14 penetration depth is also achieved, since the necessary penetration depth may  
15 be different depending on the patient's constitution. [In this instance, it can  
16 be adjusted easily and obviously.] *Its adjustment is possible, in a simple*  
17 *manner, by adjustment of the stop element which cooperates with the distal end*  
18 *segment of the first cap.*

19 Another manner of achieving the stated object is  
20 evident from the subject matter of Claim [18] 9. [An arrangement of this kind  
21 has only a few parts and thus can be produced very economically. It can be used  
22 by the patient in a simple, easily understandable fashion.

23 A further manner of achieving the stated object is  
24 evident from the subject matter of Claim 30.]

25 A needle arrangement of this kind can very easily be kept sterile until used.  
26 The covering cap is usable as an assembly aid, additionally facilitating use by  
27 the patient. *It is preferable to provide the removable closure element as a*  
28 *peelable foil, because that makes its use very simple and understandable.*

29 A further manner of achieving the stated object is evident from the  
30 subject matter of claim 23. This represents an additional safety feature, since  
31 if the cap has fallen off or, due to improper handling, has been removed, the  
32 needle is still surrounded by the integrally formed plastic spring/needle  
33 carrier structure, which represents some protection, albeit reduced, against  
34 injury or contamination from the needle, analogous to a cage surrounding the  
35 needle. This cage is not relied upon in the normal case, but rather represents  
36 a "second line of defense."

37 Each time the patient thrusts the hollow needle in, prior to an

REPLACEMENT SHEET

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1 injection, the displaceable cap is displaced in the distal direction against the  
2 force of the spring, and when the hollow needle is pulled out it moves back into  
3 its proximal end position under the action of the spring, so that the patient does  
4 not see the hollow needle during the entire injection procedure. Because of the  
5 detachable mounting on the injection device, a needle arrangement of this kind can  
6 very easily be replaced, after an injection, with a new, sterile needle  
7 arrangement.

*Brief Figure Description*

8 Further details and advantageous developments of the invention are evident  
9 from the exemplary embodiment, which is described below and depicted in the  
10 drawings and is in no way to be understood as a limitation of the invention, and  
11 from the dependent claims. In the drawings:

12 FIG. 1 is a longitudinal section through a preferred embodiment of a needle  
13 arrangement according to the present invention, in an exploded and  
14 greatly magnified depiction;

15 FIG. 2 shows a view similar to that of FIG. 1 but in the assembled state, the  
16 hollow needle being concealed by the arrangement;

17 FIG. 3 shows a view similar to that of FIG. 2 but with the needle thrust in, the  
18 penetration depth being labeled D;

19 FIG. 4 shows a view similar to that of FIG. 2, additionally depicting an outer  
20 covering cap 66 which serves to encase the needle arrangement in sterile  
21 fashion;

22 FIG. 5 shows a view of a complete, packaged needle arrangement according to a  
23 preferred embodiment of the invention;

24 FIG. 6 is a plan view looking in the direction of arrow VI of FIG. 5;

25 FIG. 7 is a view showing the adjustment of the penetration depth by way of the  
26 external covering cap 66;

27 FIG. 8 is a sectional view along line A-A of FIG. 7;

28 FIG. 9 is a sectional view along line B-B of FIG. 7; and

29 FIG. 10 is a sectional view through a defined breakpoint for a stop element,  
30 viewed along line C-C of FIG. 7.

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Detailed Description

1 In the description that follows, the terms "proximal" and "distal" will  
2 be used in the manner usual in medicine, to wit:

3 "proximal" = facing toward the patient (the end of the injection  
4 device having the needle);

5 "distal" = facing away from the patient.

6 FIG. 1 shows, on the left, a hollow needle carrier 10 made of a suitable  
7 plastic, e.g. polyethylene. Secured in this is a hollow needle (injection  
8 needle) 12 whose distal end 14 serves to pierce through the rubber membrane  
9 (not depicted) on the reservoir of an injection device 16 that is indicated  
10 only schematically in FIGS. 2 and 3.

11 An inner thread 20 of hollow needle 10, which is delimited in the  
12 proximal direction by a shoulder 22 serving as a stop, provides detachable  
13 mounting on an external thread 18 at the proximal end of injection device 16.

14 The proximal segment of hollow needle 12 is labeled 24. Extending  
15 concentrically around it, in the arrangement as shown in FIG. 1, is a plastic  
16 spring 26 that can be configured integrally with hollow needle carrier 10 and  
17 that here comprises two helical springs or spirals 26a, 26b, offset 180°, which  
18 each transition at their proximal end into a ring 28 with which they can also  
19 be integrally configured. Alternatively a separate spring, for example made of  
20 metal, could also be used here.

21 A first sleeve or cap 32 has a substantially cylindrical segment 34 whose  
22 cylindrical outer side is labeled 33 and whose cylindrical inner side 35 is  
23 configured for sliding displacement on the (also cylindrical)

1 circumference 36 of hollow needle carrier 10. First cap 32 furthermore has at  
2 its proximal end a base 40 in whose center is located a recess 42 through which  
3 proximal end 24 of hollow needle 12 can pass during an injection, as shown in  
4 FIG. 3.

5 First cap 32 has on its inner side 35 a total of three longitudinal  
6 grooves 44, only two of which are visible in FIG. 1, uniformly distributed on  
7 the circumference and providing axial guidance, i.e. rotation prevention. They  
8 coact with three projections 45, complementary thereto, on the cylindrical  
9 outer circumference 36 of hollow needle carrier 10, as clearly shown by FIGS. 2  
10 and 3.

11 First cap 32 furthermore has three barbs 46 on its inner circumference  
12 35. These barbs are also uniformly distributed on the circumference, and coact  
13 with three corresponding complementary barbs 48 on outer circumference 36 of  
14 hollow needle 10, only one of which is visible in FIG. 1. During assembly,  
15 barbs 46 slide over barbs 48 so that parts 10 and 32 are joined to one another  
16 nondetachably but axially displaceably; barbs 46, 48 form a stop in the  
17 proximal direction, as depicted in FIG. 2, and grooves 44 coact with the  
18 complementary projections 45 to provide rotation prevention for first cap 32,  
19 so that the latter cannot rotate relative to hollow needle carrier 10.

20 As clearly shown in FIGS. 1 through 3, there is located on outer  
21 circumference 36 of hollow needle carrier 10 a stop arrangement 50 against  
22 whose proximal shoulder 52 (as shown in FIG. 3) first cap 32 comes to rest with  
23 its distal end 53 when hollow needle 12 is thrust with its proximal end 24 into  
24 a body part 54 (indicated only schematically).

25 Stop arrangement 50 has here a distal stop element 56, a central stop  
26 element 58, and a proximal stop element 60. At least proximal stop element 60  
27 and central stop element 58 are each joined integrally to hollow needle carrier  
28 10 by way of a defined break point 76 (FIG. 10), and consequently can be broken  
29 off from hollow needle carrier 10 by the user. This increases insertion depth D  
30 (FIG. 3) of the proximal hollow needle portion 24. Thus either it is possible  
31 to break off only stop element 60, so that first cap

32 then comes to rest against a shoulder 61 when hollow needle 12 is thrust in; or both stop elements 58 and 60 can be broken off, in which case first cap 32 then comes to rest against a shoulder 62 when hollow needle 12 is thrust in. In the latter case, the maximum penetration depth is attained.

FIG. 4 shows, at left, hollow needle carrier 10 on whose circumference stop elements 56, 58, 60 and 56, 58', 60, 56", etc. are arranged at uniform spacings of 120°. FIG. 6 shows the three stop elements 56, 56', and 56" in a plan view according to arrow VI of FIG. 5.

FIG. 4 shows that an outer covering cap 66, which provides sterile covering of the needle arrangement, is also provided. Outer covering cap 66 is depicted in FIG. 4 partially in longitudinal section, and it is evident that its cylindrical inner recess 68, which in the case of the complete needle arrangement shown in FIGS. 5 and 6 is slid over the cylindrical outer side 33 of first cap 32, has three longitudinal grooves 70 which are distributed uniformly on the circumference of inner recess 68 and are dimensioned such that they can be slid over stop elements 56, 58, 60, 56', 58', 60', 56" etc., as is particularly clearly evident from FIG. 6.

FIG. 5 also shows a protective film 71 with which, in the complete needle arrangement, the opening (FIG. 5, left) of outer covering cap 66 can be sealed in sterile fashion. This film is welded on or adhesively bonded on, and is torn off before use. Film 71 is not depicted in FIG. 6.

FIG. 7 shows how outer covering cap 66 can be slid axially onto first cap 32 in the direction of arrow 72, arriving at a position 66' which is indicated in FIG. 7 with dot-dash lines and is depicted in section in FIG. 8, and in which its longitudinal grooves 70 are in engagement with stop elements 60, 60', 60". If outer covering cap 66 is then rotated in the direction of rotation arrow 74 depicted in FIG. 7, stop elements 60, 60', 60" are broken off along their defined break points 76 (cf. FIG. 10), i.e. penetration depth D (FIG. 3) is correspondingly increased in the manner already described above. In the same manner, it is also possible to break

off both stop elements 58, 60 (correspondingly 58', 60', etc.), and thereby to increase penetration depth D even further.

What is described is thus a needle arrangement for an injection device 16. It has a hollow needle carrier 10 on which a hollow needle 12 is mounted and which is configured for detachable mounting on injection device 16. The arrangement has a cap 32 that is arranged on hollow needle carrier 10 displaceably approximately parallel to the longitudinal extension of hollow needle 12, is equipped at its proximal end segment with a passthrough opening 42 for hollow needle 12, and in its proximal end position substantially conceals hollow needle 12. A compression spring 26 is arranged between hollow needle carrier 10 and cap 32 in order to displace cap 32 into its proximal end position. Also provided is a covering cap 66 which surrounds the displaceable cap 32, hollow needle 12, and hollow needle carrier 10, and on its open side is sealed in sterile fashion by a tear-off sealing member 71. A needle arrangement of this kind can easily be replaced after an injection. It improves compliance because the patient does not at any time see hollow needle 12. The compression spring can be configured as plastic spring 26. It is preferably integral with hollow needle carrier 10, which simplifies manufacture.

Many other variants and modifications are, of course, also possible within the scope of the present invention.